UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,761	02/07/2005	Bernard Charles Sherman	PT-2099001	1380

23607 7590 05/28/2009

Heenan Blaikie LLP
175 COMMERCE VALLEY DRIVE WEST
THORNHILL, ON L3T 7P6
CANADA

EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,761	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicant's Request for Continued Examination (RCE) and Remarks filed 23 February 2009. Said remarks and amendments are entered on the record. The Examiner further acknowledges the following:

No claims have been amended, added or cancelled.

No new matter has been added.

As such, claims 1, 3-5 and 7-11 continue represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicant's amendments to the Abstract of the Invention render the objection to the Specification moot. Thus, said objections have been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 21 October 2008:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships missing particularly from claims 1 and 10 are: what the instantly claimed composition further comprises if not a coating over the "uncoated particles" (i.e. what else beyond the drug and polymer are within the composition).

The remaining claims are rejected as being dependent from the rejected independent claims.

RESPONSE TO ARGUMENTS

Applicant's remarks with regard to the indefiniteness rejection of claims 1 and 10 under 35 USC 112, second paragraph, have been fully considered but they are not persuasive.

Applicant alleges 1.) that the Examiner has not specifically pointed out the location of essential subject matter with in the statements of record (i.e. the specification) and 2.) that there is nothing essential to the invention that is not the drug and the polymer.

In response, the Examiner respectfully points to Applicant's lone Example discussed over

the entirety of page 4 of the disclosure. Of particular interest is the discussion of filling the prepared granules into capsules (lines 14-15). Of further interest is the dissolution testing of the encapsulated granules per the US Pharmacopoeia (USP) (lines 19-23). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See MPEP §2111 and *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Given that Applicant's lone Example depicting a final encapsulated product discusses the use of an additional and seemingly requisite element of the invention in the capsule, it is thus interpreted by the Examiner that the recited invention omits a structurally essential element from said invention, absent evidence to the contrary.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore **maintained**.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devane et al. (USPN 6,228,398).

The instant claims are directed to a composition comprising a single population of uncoated particles of a homogenous mixture, which consists essentially of a water-soluble drug and an enteric polymer, wherein the ratio of polymer to drug ranges from greater than 4 to less than 100. Claims 3 and 4 recite narrower ranges for the ratio. Claims 5 and 7 recite size limitations to the particles formed wherein the particles should pass through a #8 mesh screen, but not through a #16 mesh screen. Per Sigma-Aldrich, the #8 mesh size corresponds to a size of 2.38 mm and the #16 mesh size corresponds to 1.19 mm (see *Particle size - sieve mesh conversion chart*). Therefore, the limitation of claim 5 is interpreted as reciting particles ranging in size from 1.19-2.38 mm. With regard to the release limitation, recited in claim 7, until some material difference in the properties of the composition is demonstrated, said limitation is considered by the Examiner to be directed toward the composition which is instantly claimed. Given that the limitation recited in claim 7 is functional, the claim is considered by the Examiner as reciting the same subject matter as claim 5. Methylphenidate is recited as the water-soluble drug and polyvinyl acetate phthalate (PVAP) is recited as the enteric polymer (claims 8 and 9). Newly added claim 10 recites the same subject matter as claims 1 and 5, further specifying methylphenidate as the water-soluble drug and reciting a drug/polymer ratio of greater than 10 to less than 50. Claim 11 recites PVAP as the enteric polymer.

The teachings of Devane are discussed above where they apply to the instant claims 1, 3 and 4, particularly in the *Response to Arguments* section. Devane further teaches multiparticulate

modified release compositions containing methylphenidate wherein said composition is applied to non-pareil seeds, which range in size up to 0.85 mm.

Devane does not expressly teach the claimed size range for the prepared granules (i.e. between #8 and #16 mesh), as instantly claimed by Applicant. Nor does Devane expressly teach methylphenidate as being exclusively mixed with PVAP to form the claimed granules.

As discussed above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising populations of particles consisting of the water-soluble drug methylphenidate and a release matrix polymer such as PVAP, as suggested by Devane, modify the levels or ratios of the ingredients, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Devane teaches, as discussed above, that the PVAP is a functionally equivalent matrix polymer to those which are expressly taught, either in the claims or in the Examples. Furthermore, in view of the Examples as well as the teachings of claims 1 and 6, an artisan of ordinary skill would have been motivated to create a first population of particles consisting of one ratio of methylphenidate to PVAP and then create a second population consisting of the same components, but mixed in a different ratio. Such a composition would not only consist of the instantly claimed components, but also possess differing polymer/active ratios, which would, in effect, demonstrate distinct release rates, thereby producing the instantly claimed bimodal release.

Regarding the polymer/drug ratio and the sized granules, since the values and formats of each parameter with respect to the claimed composition are adjustable, it follows that each is a

result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. For example, as taught in Example 1, the release characteristics of the modified release component are taught as being variable simply by changing the composition and thickness of the coating applied to the non-pareil seed. Thus, it would have been customary for an artisan of ordinary skill, to vary the amounts of methylphenidate and polymer within the composition, as well as to adjust the thickness of the composition which is applied to the seed, in order to achieve the desired component ratio and bimodal release pattern. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicant's arguments with regard to the rejection of claims 1, 3-5 and 7-11, under 35 USC 103(a) as being unpatentable over the combined teachings of Devane et al. have been fully considered but they are not persuasive.

Applicant alleges that "nowhere in Devane et al. is it taught or suggested that a *composition* may have only two ingredients (the active ingredient and a single polymer) homogenously mixed into a single population of granules" [*emphasis added*] (Remarks, pg. 6, end

of ¶2). It is further alleged that the skilled artisan would not be motivated to create two populations having the same ingredients but with different ratios in order to demonstrate bimodal release of the drug and that such a composition is not within the scope of the instant claims.

In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., that the composition may have *only* two ingredients) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Otherwise stated, the scope of Applicant's claims are more broadly recited than what is being argued in the Remarks. Applicant's claims are directed to a composition which *comprises* a single population of uncoated particles of a homogenous mixture, wherein said mixture consists essentially of a water-soluble drug and an enteric polymer [*emphasis added*]. Since the overall claimed composition is recited as comprising the particles of the homogenous drug/polymer mixture, it follows, per MPEP §2111.03, that the scope of the claims is open to including additional components (e.g. a second population of particles prepared by mixing a different ratio of the same components) within said overall composition.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure,

such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

ART OF INTEREST CITED

The Examiner cites the invention of Mitra et al. (US Pre-Grant Publication N° 2001/0046472) as being art of interest with regards to the instant application.

CONCLUSION

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615